Bringing palliative care for dementia into agreement with their wishes and needs: development and evaluation of Decidem

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42489

Source
ToetsingOnline

Brief title
Decidem

Condition

- Other condition

Synonym
advance directive, end of life care, living will

Health condition

advance care planning, shared decision making, palliatieve zorg

Research involving
Human

Sponsors and support

Primary sponsor: IQ-Healthcare
Source(s) of monetary or material Support: subsidie van ZonMw

Intervention

Keyword: advance care planning, dementia, palliative care, shared decision making

Outcome measures

Primary outcome

The main study parameters are the differences between the intervention group

and the control group regarding the patient*s wishes/goals discussed, recorded

and respected.

Secondary outcome

The secondary study parameters are: the effect of the intervention on the

patient*s quality of life and their satisfaction with care, the caregivers

burden and satisfaction with care and the healthcare professionals satisfaction

with care.

Study description

Background summary

Patients with dementia have limited access to palliative care. At the end of their lives, aggressive and unwanted interventions like resuscitation and hospitalization regularly take place. Physical symptoms in patients such as pain or dyspnea and neuropsychiatric symptoms and depression in both patients and family caregivers are often undertreated. This threatens the quality of life of dementia patients and their family caregivers. Palliative care can bring actual care into agreement with patients* and caregivers* needs and wishes. Therefore an innovative intervention in dementia care combining the strengths of advance care planning (ACP) and shared decision making (SDM) called Decidem will be developed. The research aim of this project is to evaluate its effects on care, patients and

caregivers, and costs. We hypothesize that Decidem will bring actual care into agreement with patients* and caregivers* wishes/preferences and needs.

Study objective

The objectives of this patient-centered, personalized intervention are to increase the satisfaction with care of patients with dementia, decrease caregivers* burden and increase quality of life. We also hope to decrease under- and overtreatment, hospitalizations and unplanned visits and reduce costs.

Study design

The effects of Decidem will be studied in a cluster-randomized trial with six months follow-up. Thirty dyads of GPs
and PCNs will be invited to participate. Each dyad will be invited to include five dementia patients and their family caregivers. After patient selection, 15 GP/nurse dyads will be randomly allocated to the intervention group and the other 15 to the control group using study wise minimization. Intervention group dyads will be exposed to the intervention. Control group dyads receive no training or other support (usual care).

Intervention

Primary healthcare professionals will be trained in using shared decision making and advance care planning according to a structured protocol and with the use of ZWIP (an existing ICT tool for the use of ACP en SDM in primary healthcare). The dementia patients and their caregivers in the intervention group will receive care according to this protocol. The dementia patients and their caregivers in the control group will receive care as usual.

Study burden and risks

In order to explore the barriers and facilitators and discover additional factors which will influence the implementation and use of advance care planning and shared decision making by the healthcare professionals, two types of interviews will be conducted. Focus group interviews will be used for retrieving information from the healthcare professionals. Patients with dementia and their caregivers will be interviewed in the comfort of their own homes.
The focus group interviews will take about 2 hours and, except from the invested time, will not be associated with any burden or risks. The interviews with patients with dementia and their caregivers will take about one hour and apart from the invested time may cost some burden because of the issues (their experiences with their disease and the care they received) which are going to be discussed.

The healthcare professionals who are in the intervention group will have to attend two meetings in order to be trained in using the intervention protocol. They will also have to complete the Satisfaction with dementia care: visual analogue scale, the easycareTOS (an instrument for geriatric assessment and frailty identification in primary care), the Clinical dementia rating scale, the Recource Utlity in Dementia (RUD) and the EQ-6D. Of course they will also have to use the intervention protocol when treating the dementia patients which will contain at least to meetings with the patient and their primarycariver in order to discuss their future healthcare goals..
The healthcare professionals in the control group will have to complete the satisfaction with dementia care: visual analogue scale. The easycareTOS questionnaire, the Clinical dementia rating scale, the EQ-6D and the Recourse Utility in Dementia care (RUD).
All patients in the control and intervention group will have to complete the quality of life and depression: DEMQOL, the Satisfaction with care questionnaire and the IMTA MCQ. They will also be asked to complete the EQ-6D questionnaire and the Clinical Dementia rating Scale. Their caregivers will be asked to complete the Burden: sense of competence questionnaire and the Satisfaction with care: Short assessment of patient satisfaction, The IMTA MCQ and the Clinical Dementia Rating Scale. The patients and the primary caregivers in the intervention group are invited to attend two meetings with their GP or primary care nurse for a discussing their future healthcare goals. The patients in the control group receive care as usual.
There are no risks involved for the participating patients in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients older than 65 years
Community dwelling patients or patients living in a home for the elderly under the care of a genral practitioner
Primarycarers of the patients mentioned above

Exclusion criteria

People who do not speak dutch
patients with a life expectancy less than 6 months

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2016

Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52613.091.15